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RECORD OF ORAL HEARING
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex Parte ANTHONY NICOLAS KALLOO, and
SERGEY VENIAMINOVICH KANTSEVOY

Appeal 2009-006379
Application 09/815,336
Technology Center 3700

Oral Hearing Held: March 11, 2010

Before LINDA E. HORNER, KEN B. BARRETT, and
FRED A. SILVERBERG, *Administrative Patent Judges*.

APPEARANCES:

ON BEHALF OF THE APPELLANT:

MICHELLE N. LESTER, ESQUIRE
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1 The above-entitled matter came on for hearing Thursday, March 11,
2 2010, commencing at 1:25 p.m., at the U.S. Patent and Trademark Office,
3 600 Dulany Street, Alexandria, Virginia, before Timothy J. Atkinson, Jr., a
4 Notary Public.

5 THE USHER: Calendar No. 46, Appeal No. 2009-006379,
6 Ms. Lester.

7 JUDGE HORNER: Thank you. Good afternoon, Ms. Lester.

8 MS. LESTER: Good afternoon.

9 JUDGE HORNER: Do you happen to have a business card you could
10 provide to the court reporter?

11 MS. LESTER: I sure do.

12 JUDGE HORNER: Great. Thank you.

13 MS. LESTER: For once, I'm prepared with my card.

14 JUDGE HORNER: You can begin whenever you're ready. We've
15 had a chance to review the case.

16 MS. LESTER: Thank you. All right, the Invention that is the subject
17 matter of this Application relates to a method for either inspecting or
18 conducting a surgical procedure within the cavity of a mammal, but we're
19 particularly thinking about the peritoneal cavity, what most people would
20 call the abdominal cavity.

21 Conventionally, when you wanted to do a procedure in the peritoneal
22 cavity, an incision would be formed through the abdominal wall, spread the
23 incision. You go in, you do what you want to do, you close up the patient.
24 The problem with that is when you cut the muscle, the healing time is
25 extended. You obviously have a visible scar which is unattractive. Most
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1 people, if they have a couple of extra pounds on them, it's going to be on the
2 belly, and when you cut through fat you end up having a rather ugly divot in
3 the fat where a surgical incision has been made.

4 Because of those factors and also the chance for infection, the need to
5 change dressings, things of that sort, as surgical techniques progressed they
6 went to what you might call laparoscopic techniques, where you would
7 make perhaps two or three small incisions. You kind of blow up the
8 abdomen so you can see what you're doing. That way, you have smaller
9 incisions. It lessens the healing time, but you still have exposed wounds,
10 you still have the chance for infection, you still have ugly scarring and the
11 potential for dimpling in heavier patients.

12 What Dr. Kalloo and his colleagues developed was a technique
13 whereby, rather than invading the external abdominal wall, you go through a
14 natural body orifice, and they envision going through the mouth and
15 esophagus, into the stomach, going through the stomach wall, doing what
16 you wanted to do, closing up the hole in the stomach wall, and you're done.

17 Interestingly, whereas on your skin you have a number of nerves and
18 you can feel every sort of invasion that has been made through it, the
19 stomach -- in fact, most of the digestive tract -- the nerves are pretty much
20 limited to distension. If you have gas or something else that is swelling you
21 up, then you're going to have pain. But actually, there's almost no
22 discernible pain or very little pain from simply a cut, so you have no
23 discomfort, you have no wounds to dress over time, and obviously you have
24 no visible scars.

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1 Now, with what at the time -- and this was developed over a decade
2 ago initially. The Application was filed -- Provisional Application was filed
3 10 years ago. When you are dealing with a brand-new technique, you have
4 to come up with not only a practical way -- it's a great idea, but you have to
5 come up with a practical way of implementing it, and when you're doing
6 something brand-new there's no instruments specifically designed for it. So
7 you either have to adapt existing instruments for your new technique or
8 come up with entirely new instruments. You also have to deal with the
9 uniqueness of the approach.

10 So in Dr. Kalloo's implementation, he envisioned that you need a
11 flexible conduit through which you are going to have a sterile path to the
12 surgical field; that you would need to go through the stomach wall or other
13 digestive tract wall; and have that sterile path go through the wall. You want
14 things to stay where you put them, and then ultimately you need to make
15 sure you're minimizing the damage inside and you can see what you're
16 doing. So he proposed to have a flexible conduit. It's conducted to
17 wherever you've decided you're going to go through the digestive tract wall.
18 Then through that conduit, in close proximity to the digestive tract wall, you
19 form an incision. You dilate that incision with a balloon. The reason for
20 that is so that you don't have undesired tearing of the tissue. If you force
21 something through a hole that's too small, it's going to tear unpredictably and
22 it will have a stress point at the end of the tear, so it's easy for it to tear
23 further. If you form an incision that's defined and then you gently dilate it,
24 you'll be able to advance surprisingly large instruments through the dilated
25 opening.

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1 Once it's incised, it's dilated with a balloon. He then advances the
2 flexible conduit through the incision, and he anchors it to the stomach wall.
3 You then have a path directly from outside the patient into the cavity that
4 you've accessed, and then you can conduct whatever procedure you like or
5 just look at what's going on. And when you've completed it, you just reverse
6 those steps.

7 That's what we have claimed in our Independent Claim, those series of
8 steps. We have in other claims specifics about some of the attributes of the
9 procedure and the instruments used. Most notably are the Claims -- I
10 believe it's 13, 15, 18, and 19 -- that are specific to the forming of the
11 incision and dilating it. They actually developed a new instrument in order
12 to be able to do this effectively through the endoscope that's placed in the
13 flexible conduit, and that is they have a needle knife device where they have
14 a needle knife conduit where you hide the needle until you're ready to use it.
15 The needle can pop out, do its work of cutting. Then you can retract it, even
16 advance the conduit through the incision that you formed, and there's a
17 balloon on the exterior of that conduit. You can do the dilation that you
18 wish, then you can remove the needle. Before or after doing the dilation,
19 you can insert a guide wire to guide other instruments through. So those are
20 the main features that we have in the Independent Claim, and then some key
21 Dependent Claims.

22 The Examiner has cited Wilk as a primary reference against
23 Applicant's Claims. Wilk does teach the concept of a procedure conducted
24 in the abdominal cavity that is approached through a natural body orifice.
25 As I mentioned, whenever you come up with a new concept, implementing it
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1 can be the challenge, and they say the devil's in the details. Unfortunately,
2 Wilk doesn't give a whole lot of details about how to implement this. I've
3 read it several times and I still can't figure out how the suction attaches his
4 tube to the stomach wall, but somehow he latches onto the stomach wall and
5 then, while somehow staying sucked up against the stomach wall, he then
6 can do procedures. He just pokes through and does what he wants to do.

7 Our objection to the Examiner's rejection based on Wilk was that,
8 firstly, the flexible conduit Wilk teaches never extends through the incision
9 into the abdominal cavity.

10 JUDGE HORNER: It's my understanding that the Examiner -- at least
11 after reading the Examiner's rejection a few times, I think what the Examiner
12 was saying was not that the tubular --

13 MS. LESTER: I think I know where you're going.

14 JUDGE HORNER: Not the tubular member --

15 MS. LESTER: But the sheath of the endoscope?

16 JUDGE HORNER: It's the sheath of the endoscope, so can you
17 address that?

18 MS. LESTER: Sure. I believe he said that in his Answer when he
19 brought that up. The endoscope, he says, has a sheath, but there's no
20 disclosure whatsoever of the sheath of the endoscope ever being in any way
21 affixed to anything, certainly not anchored to the stomach wall. And it
22 would seem, just off the cuff, that that would be precluded by the suction
23 that he has with his tube. Somehow that's stuck against the inside, so I
24 don't -- you know, you can -- I guess if somehow you've latched onto the
25 inside, you can pass something through, you can pass it out, but I don't know

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1 how you might anchor yet another structure to it. But that's never
2 mentioned. It's simply mentioned that the endoscope has a sheath.

3 JUDGE HORNER: It does mention that the endoscope goes through
4 the incised opening.

5 MS. LESTER: Yes, the endoscope does go through it into the cavity.
6 One of the issues that we had, of course, was the lack of passage of what
7 we've referred to as the flexible conduit through the incision. If you
8 consider the endoscopic sheath to be a flexible conduit, there's no teaching
9 in Wilk anchoring it to the stomach wall. Even if you were to say well,
10 somehow you've got to lock it in place perhaps, we have the additional
11 limitations that the incision is dilated after it's formed and that it's
12 specifically dilated with a balloon.

13 JUDGE HORNER: And the Examiner relied on McNeely for those
14 two --

15 MS. LESTER: Did rely on McNeely for the dilation concept.
16 McNeely is, in some respects, related and in some respects, I think, very
17 different, and I -- I'd say our principal objection to McNeely is the Examiner
18 knows what we're disclosing, knows what's not in Wilk, and he started
19 picking and choosing.

20 As I said, any new surgical technique you're going to look around and
21 see what techniques are known that I might be able to adapt to this, what --
22 do I have to develop something entirely new. McNeely actually -- I don't
23 think you can only look at an isolated feature. He's actually going through
24 the muscle wall and through the stomach wall. Now, you need to be sure
25 that you're going to be going into the stomach, I guess. He does anchor the
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1 abdominal wall to the stomach wall in a couple of different places, and then
2 he actually dilates in an approach where he has a series of dilators. You put
3 one over the guide wire, you put the next bigger one over, the next bigger
4 one over, the next bigger one over, and finally you do a balloon. It's easy to
5 do that when you're outside the patient and you're watching what you're
6 doing and you can easily slide instruments back and forth. But also bear in
7 mind that McNeely is having to dilate musculature, connective tissue, a lot
8 of tissues that are involved on the outside of the patient, outside the stomach
9 wall that may or may not have anything to do with dealing with the stomach.

10 Now, again, we did recognize -- and I don't know when Dr. Kalloo
11 recognized this. He did pig studies long before the Application was
12 approved for filing in the first instance. He may have found if you don't
13 dilate you're going to have an uncontrolled tear in the stomach wall and a
14 larger wound, so he at some point recognized that you need to deal with that.
15 Even though the stomach is easily distendable, he recognized that you
16 needed to do it in that particular environment.

17 McNeely's dealing with a different environment. He's not dealing
18 with passing an endoscope through a flexible conduit, he's not dealing with a
19 surgical procedure. He's simply dealing with a feeding tube that is stuck
20 through the musculature of the abdomen. So yes, it teaches dilation is not a
21 brand-new concept. It's been around anytime you're poking something
22 through a hole too small to fit. But the adaptation to Wilk, we think, is
23 strained.

24 Again, even beyond that, we do have features in Dependent Claims
25 that we feel are completely unique. Even if it's felt that the dilation aspect,

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1 particularly dilation with a balloon, is not novel, even though we feel it is,
2 the concept of providing a needle knife device that has the needle within a
3 conduit, with a balloon, so you can accomplish incision immediately
4 followed by dilation, immediately followed by a guide wire was a device
5 that we don't know to exist in surgical devices and is uniquely adapted to the
6 particular environment in which we're working.

7 JUDGE HORNER: Any questions?

8 JUDGE BARRETT: None I can think of.

9 JUDGE HORNER: No, I don't think we have anything further.

10 MS. LESTER: Okay. Thank you very much.

11 JUDGE HORNER: Thank you for your time.

12 Whereupon, the proceedings, at 1:38 p.m., were concluded.
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